510(k) Summary
for the A-Wedge Anterior Interbody System

SEP - 8 2011

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the A-Wedge Anterior Interbody System

1. GENERAL INFORMATION

Date Prepared: April 19, 2011

Trade Name: A-Wedge Anterior Interbody System (A-Wedge A.I.S.)

Common Name: intervertebral body fusion device

Classification Name: Intervertebral body fusion device - lumbar

Class: II

Product Code: MAX

CFR section: 21 CFR section 888.3080

Device panel: Orthopedic

Legally Marketed Predicate Devices: Lucent Straight Intervertebral Body Fusion Device - K071724/ K081968
BRANTIGAN I/F CAGE - P960025
CoRent System - K071795/K100043

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2. DEVICE DESCRIPTION

The A-Wedge Anterior Interbody System (A-Wedge A.I.S.) implants were developed as implants for the posterior stabilization of the lumbar spinal column. The body is rounded trapezoidal in shape with two large windows allowing placement of bone graft and facilitating fusion. The superior and inferior surface of the device has a pattern of teeth to provide increased stability and inhibit movement of the implant.

Materials:
PEEK-OPTIMA LT1 polymer (ASTM F2026)
ELI grade Ti-6Al-4V (ASTM F136)

Function:
The A-Wedge A.I.S. devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The A-Wedge A.I.S. is substantially equivalent to the Lucent Straight Intervertebral Body Fusion Device (K071724/ K081968 - Spinal Elements, Inc), BRANTIGAN I/F CAGE (P960025 - DePuy Spine) and CoRent System

(K071795/K100043 – NuVasive, Inc.) in terms of intended use, design, materials used, mechanical safety and performances.

The following devices were used as predicates for testing acceptance criteria:

- RAY THREADED LUMBAR FUSION CAGE (P950019)
- BRANTIGAN I/F CAGE (P960025)

4. INTENDED USE

The A-Wedge Anterior Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). A-Wedge Anterior Interbody System implants are to be used with autogenous bone graft and implanted via an anterior or anterolateral approach. The Anterior Interbody System implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

5. NON-CLINICAL TEST SUMMARY

The following tests were conducted:

- Static and dynamic compression per ASTM F2077
- Subsidence per ASTM F2267

The results of this testing indicate that the ART2 system is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

The A-Wedge A.I.S. is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Mr. J.D. Webb
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Round Rock, Texas 78681

SEP - 8 2011

Re: K111166
Trade/Device Name: A-Wedge Anterior Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 22, 2011
Received: July 27, 2011

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K111166

Device Name: A-Wedge Anterior Interbody System

Indications for Use:

The A-Wedge Anterior Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). A-Wedge Anterior Interbody System implants are to be used with autogenous bone graft and implanted via a transforaminal approach, or an open posterior or lateral approach. The A-Wedge Anterior Interbody System implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111166